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PATENT 3-10-94

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit:

1502

Examiner:

Inventor:

Boris E. Goldman

Serial No:

08/020,202

Filed:

February 19, 1993

For:

COMPOSITIONS AND METHODS FOR

PROMOTING HAIR GROWTH

1204

INFORMATION Press

DISCLOSURE STATEMENT

RECEIVED

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GROUP 150

CERTIFICATE OF MAILING

By Olam J. Sneet

Hon. Commissioner of Patents and Trademarks Washington, D.C. 20231

Dear Sir:

In compliance with 37 C.F.R. §1.56, the Examiner is hereby respectfully advised that the art listed on the attached sheets is known by or has come to the attention of Applicant and is being submitted herewith for consideration by the Examiner. Applicant has identified the art by author, title, journal, volume, page number and date on the PTO-1449 form attached hereto. Copies of all the listed references (except where noted) are included herewith.

Young, M.W., "American Association of Anatomists," *Anatomical Record* 100:728 (1948).

Young, M.W., "American Association of Anatomists," *Anatomical Record* 97:378 (1947).

Szasz, T.S. et al. "A Theory of the Pathogenesis of Ordinary Human Baldness" Archives of Dermatology and Syphilology 61:34-48 (1950).

Orentreich, N. "Autografts in Alopecias and Other Selected Dermatological Conditions," *Ann. NY Acad. Sci.* 83:463-479 (1959).

Orentreich, N. et al. "Biology of Scalp Hair Growth," *Clin. Plast. Surg.* 9:197-205 (1982).

Zapocosta, A.R. "Reversal of Baldness in Patient Receiving Minoxidil for Hypertension," *New Eng. J. Med.* 303:1480-1481 (1980).

Hamilton, J.B. "Patterned Loss of Hair in Man: Types and Incidence," *Ann. NY Acad. Sci.* 53:709-728 (1951).

Klemp. P. et al., "Subcutaneous Blood Flow in Early Male Pattern Baldness," *J. Invest. Derm.* 92(5):725-726 (1989).

Juri, J. et al., "Temporo-Parieto-Occipital Flap for the Treatment of Baldness," *Clin. Plas. Surg.* 9:255-261 (1982).

Lemke, R. et al., "Noninvasive Ptco₂ Initial Slope Index and Invasive Ptco₂ Arterial Index as Diagnostic Criterion of the State of Peripheral Circulation," *Crit. Care Med.* 16:353-357 (1988).

Kram, H.B. et al., "Assessment of Peripheral Vascular Disease by Postocclusive Transcutaneous Oxygen Recovery Time," *J. Vasc. Surg.* 1:628-634 (1984).

Wester, R.C. et al., "Minoxidil Stimulates Cutaneous Blood Flow in Human Balding Scalps: Pharmacodynamics Measured by Laser Doppler Velocimetry and Photopulse Plethysmography," *J. Invest. Derm.* 82:515-517 (1984).

Dingman, R.O. et al., "The Surgical Repair of Traumatic Defects of the Scalp," *Clin. Plast. Surg.* 9:131-144 (1982).

Hunt, et al., "The Effect of Varying Ambient Oxygen Tensions on Wound Metabolism and Collagen Synthesis," *Surg. Gyn. Ob.* 135:561-566 (1972).

Marshall, R.C. et al., "Structure and Biochemistry of Mammalian Hard Keratin," 4:47-83 (1991).

Jonsson, K. et al., "Tissue Oxygenation, Anemia, and Perfusion in Relation to Wound Healing in Surgical Patients," *Ann. Surg.* 214:605-613 (1991).

Buxman, M. et al., "Keratin Cross-Linking and Epidermal Transglutaminase," *J. Invest. Derm.* 65:107-112 (1975).

Buxman, M.M., "Enzymes of Keratinization," Internat. J. Derm. 20:95-98 (1981).

Sawaya, M.E. et al., "Immunohistochemical Distribution of Aromatase and 3B-hydroxysteroid Dehydrogenase in Human Hair Follicle and Sebaceous Gland," *J. Cutan. Pathol.* 19:309-314 (1992).

Sawaya, M.E. "Steroid Chemistry and Hormone Controls During the Hair Follicle Cycle," *Ann. NY Acad. Sci.* 642:376-383 (1991) (Abstract).

Sawaya, M.E. "Steroid Chemistry and Hormone Controls During the Hair Follicle Cycle," *Ann. NY Acad. Sci.* 642:376-383 (1991).

Schweikert, H.U. et al., "Regulation of Human Hair Growth by Steroid Hormones. 1. Testosterone Metabolism in Isolated Hairs," *J. Clin. Endocrin. Metab.* 38:811-819 (1974).

Orfanos, C.E. "Lokaltherapie der Alopecia Androgentica mit 17 α-Ostradiol," Dermatologica 161:124-132 (1980).

Takayasu, S. et al., "The Conversion of Testosterone to 17β -hydroxy- 5α -androstan-3-one (Dihydrotestosterone) by Human Hair Follicles," *J. Clin. Endocrinol. Metab.* 34:1098-1101 (1972).

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Herring, B.D., "Unravelling the Pathophysiology of Male Pattern Baldness," *J. Nation. Med. Assoc.* 77:142 and 145 (1985).

Freedberg, I.M., "Biochemistry of Keratinization in Hair: Protein Synthesis, Pathways and Controls," pp. 105-112.

Applicant is attempting to locate the following references and will submit them to the United States Patent and Trademark Office as soon as they become available. The references are set forth on the PTO-1449 form submitted herewith.

Hamilton, J.B., Am. J. Anat. 71:451-480 (1942).

Jonsson, K. et al., Ann. Surg. 214, 5:605-613 (1991).

Bruchovsky, N. et al., J. Biol. Chem. 243:2012 (1968).

Tang, S. et al., J. Biol. Chem. 244:6584 (1969).

Applicant believes that the following references are not material to the present invention but merely contain general background information and therefore these references are not cited on the PTO-1449 form and copies are not submitted herewith. If the Examiner requests copies of these references, it is requested that the Examiner please notify Applicant.

Lehninger, A.L., Biochemistry, 3rd ed., pp. 126-135 (1988).

Devlin, T.M., *Textbook of Biochemistry with Clinical Correlations*, 3rd ed., pp. 66-67 (1992).

Wilson, J.P. et al., Williams Textbook of Endocrinology, 8th ed., pp. 805-809 (1992).

Shein, M., Ueber die Entstehung der Glatze, Wien. KLIN. Wchnschr. 16, 611-615 (1903).

Zur Frageder Entstehung der Glatze, Wien. KLIN. Wchnschr. 16, 968-970 (1903)

It is Applicant's opinion that the claims presently on file are patentably distinguishable from these references. The above references are being cited only in the interest of candor and without any admission that they constitute statutory prior art or contain matter which anticipates the invention or which would render the same obvious, either singly or in combination to a person of ordinary skill in the art.

In the event a first Office Action on the merits has been mailed in the above identified application prior to the Certificate of Mailing date set forth above, the Commissioner is hereby authorized to charge the fee due under 37 C.F.R. 1.17(p) to Applicants' attorneys' Deposit Account No. 08-0750. A copy of this Information Disclosure Statement is enclosed for this purpose.

Respectfully submitted,

HARNESS, DICKEY & PIERCE Attorneys for Applicant

Reg. No. 36,683

I. Snut

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Attorney Docket No. 7019-00001